

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Browning

CONFIRMATION NO.: 1575

APPLICATION NO.: 10/510,488

GROUP NO.: 4185

FILING DATE: March 28, 2005

EXAMINER: Burk, Catherine E.

TITLE: Apparatus and Method for Treating Female Urinary Incontinence

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

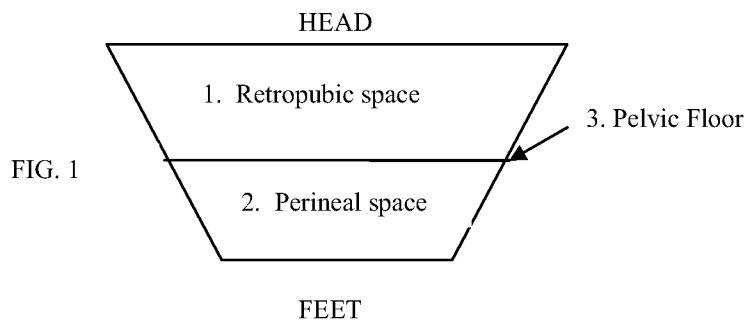
**DECLARATION OF JAMES J. BROWNING, M.D. UNDER 37 C.F.R. §
1.132**

Dear Sir:

I, James Browning, M.D., hereby declare and state as follows:

1. I am a recognized expert in the field of gynecology and particularly, in the repair of urinary incontinence in women. I have been practicing as a physician in this field since 1986, before the priority date of the present patent application number 10/510,488 ("the present application"). My *curriculum vitae*, which includes my educational and employment history as well as a biographical summary of my professional experience, is attached as Exhibit A. At present, I am the founder and Chief Technology Officer of Mpathy Medical Devices, Ltd.
2. I am the sole named inventor in the present application. I understand that the present application has an effective filing date of April 11, 2003, and a priority date of April 11, 2002.
3. I have been asked as a person skilled in the art of surgical repair of female urinary incontinence to explain the various surgical methods for repair of female urinary incontinence and the meaning of scientific terminology as it relates to the female anatomy of the pelvic region.

4. The pelvic region of an adult female includes two soft tissue spaces, the retropubic space (“1” in FIG. 1 below) and the perineal space (also known as the “perineum,” “2” in FIG. 1). In a standing adult female, the retropubic space lies above the perineal space. The retropubic space as well as the tissues of the retropubic space lie behind the pubic bone, but do not include the pubic bone. The “levator ani” or “pelvic floor” or the “pelvic diaphragm” (which can be represented in incontinence surgery by the endopelvic fascia) separates the retropubic space from the perineal space and is shown as “3” in FIG 1.



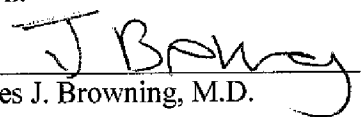
5. The perineal space contains the soft tissues of the perineum. The perineal space is the area defined by the pubic arch and the arcuate ligament of the pubis, the tip of the coccyx, the inferior rami of the pubis and ischium, and the sacrotuberous ligament. The perineal space includes muscles such as the obturator internus. The pubic bone is not part of the perineum and is not a soft tissue. Accordingly, the pubic bone is not a soft tissue of the perineum. Further, neither the retropubic space, rectus sheath, pectineal ligament, or proximal urethra is located in the perineum.
6. The bladder lies within the retropubic space, with the portion of the urethra closest to the bladder (“proximal urethra”) lying within the retropubic space and the portion of the urethra farthest from the bladder (“distal urethra”) lying in the perineal space.
7. I am familiar with the teachings of Annis *et al.* (U.S. Patent No. 4,857,041, “Annis”). From reading Annis, Annis’ cuff is implanted to “extend wholly or partly around the proximal urethra” (Annis, col. 3, lines 12-14) and can be tethered to “adjacent paraurethral structures” (Annis, col. 3, lines 23-24). From reading Annis, the paraurethral structures to which Annis

teaches tethering the cuff are in the retropubic space because the proximal urethra which Annis' cuff surrounds is in the retropubic space and the tethering sutures extend upward which can only be into the retropubic space.

8. I further declare that all statements made in this Declaration are of my own knowledge, are true, and that all statements made on information and belief are believed to be true. Moreover, these statements were made with the knowledge that willful false statements and the like made by me are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: March 20, 2009

By: _____


James J. Browning, M.D.

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Qualifications

MB ChB, Bachelor of Medicine/Surgery, University of Manchester 1980
FRCS, Fellow of the Royal College of Surgeons, Edinburgh 1984
FRCOG, Fellow of the Royal College of Ob/Gyn UK 1988 (2000)
Certificate of Completed Specialist Training in Ob/Gyn 1992
MD, Doctor of Medicine (Research) University of Bristol 1993
MFFP, founder Member of Faculty of Family Planning/Reproductive Health
MBA, Strathclyde Business School 1999

Employment

Nov 2008-present
Chief Technology Officer and Founder Mpathy Medical Devices Ltd.

(also Chairman, Ocutec Ltd.)

Jun 2000 - Nov 2008
Managing Director(CEO) of Gyne Ideas Ltd/Mpathy Medical Devices Ltd

Oct 97 – Jun 2000
Director of New Businesses (Gynecare and Mitek) Ethicon Ltd.

Oct 94 – Sept 97
Research & Development Director, Ethicon Ltd, Johnson & Johnson

Dec 91 – Sept 94
Consultant and Senior Lecturer (Chief/Assoc. Prof.) Ob/Gyn, University of Bristol. Specialist interest in incontinence and endosurgery

Dec 90 – Dec 91
Specialist (Chief) Ob/Gyn National Women's Hospital, Auckland NZ

Aug 80 – Nov 90
Training posts in Medicine, Surgery, Urology and Ob/Gyn in Manchester, Bristol, Southampton, Oxford

Major Achievements

Personal development of 6 patented surgical technologies
Recipient of 7 major research awards
Development of pioneering gyne endosurgery unit, Bristol
Setup of national incontinence and endosurgery units, Auckland
Founder member of British Society of Gyne Endoscopy
Successful setup and leadership of Gynecare UK and triple digit growth 1998, 1999
Commercialisation of TVT, invention of Gynemesh

Holder of 31 granted patents including only granted patents on minislings and ultralightweight mesh
Author of 67 academic papers, 4 books / chapters

Competencies

Unique clinical and business insight into innovations in healthcare provision, particularly gynaecology, surgery and medical device invention.
Understanding of R & D, Clinical Trial, regulatory and marketing pathways
Demonstrable high achievement and delivered business results at every stage of diverse career: surgery, R&D, new business setup
Entrepreneurial approach: preference for 3-5 year high growth projects.
Charismatic team leader, lucid presenter
Strong business, medical and academic networking
Linguistic competence: German, French